ThermoFisher SCIENTIFIC
The world leader in serving science

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Company data are stored at the Register of Legal Entities of the Republic of Lithuania

Thermo SCIENTIFIC

URGENT: DEVICE RECALL

Dynabeads™ HLA Class II and *Dynabeads™ HLA Cell Prep II*

PRODUCT DESCRIPTION	CATALOG NUMBER	LOT NUMBER	PRODUCT DESCRIPTION	CATALOG NUMBER	LOT NUMBER
Dynabeads™ HLA Class II	21003	00461955	Dynabeads™ HLA Cell Prep II	21903	00469606
		00477414			00477408
		00480193			00480204
	21004D	00461951		21904	00455989
		00469604			00461965
		00477401			00469615
		00480209			00492942

May 12, 2017

Dear Valued Customer,

Our records indicate that you purchased either our Dynabeads™ HLA Class II or Dynabeads™ HLA Cell Prep II product. We are writing to notify you about quality findings for these product Lots which are listed in the table above.

We have recently identified an impurity (bacterial endotoxins) in the raw material used for the final formulation of the finished product. Our investigation has determined that the presence of these endotoxins along with any deviation from the recommended cell isolation temperature in the user manual (e.g. performing some steps or storing product at room temperature) may reduce cell viability and lead to failure of the negative control.

The affected lots have been removed from our inventory, and we are implementing additional QC measures to prevent this issue from occurring again in the future.

Please discontinue use of this material immediately and destroy any remaining stock in accordance with local laws and regulations. Record the quantity of product destroyed on the enclosed Customer Response Sheet. You may choose to have the product replaced or be credited for the value of the material destroyed. The completed form may be sent by facsimile at +370 5 2602142 or by emailing a scanned copy to info.baltics@thermofisher.com. If you have any questions, call Technical Support, at +1 (818) 702-0042.

Please notify all affected users in your facility of the recall. If you have shipped this material outside of your facility, you must also notify those users of this recall.

We appreciate your assistance and apologize for the inconvenience this matter may have caused.

Sincerely,

Edita Aukštikalnienė
Director, Quality Assurance
Molecular Biology
Life Sciences Solutions
Thermo Fisher Scientific

PLEASE FORWARD TO END USER

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CUSTOMER RESPONSE SHEET

Recall Of:	
Bill To:	
Invoice:	
Invoice Date:	
Address:	
Attention:	
Ordered By:	
Purchase Order No.	

Please complete this form as soon as possible.

WE HAVE DISCARDED THE FOLLOWING PRODUCT:

Remaining Inventory X mL	
Catalog No.	_____
Control/Lot No.	_____

I request the following: **ALL RECALLS DO NOT WARRANT REPLACEMENTS**	☐ No - Charge Replacement ☐ Credit my account

I have shipped this lot to other facilities:	☐YES	☐NO
If YES, I have notified those facilities of this recall:	☐YES	☐NO
If YES: Describe method of notification:		
Number of customers/facilities notified:		
Date notified:		

Product End User: _____
Date: _____

(Signature)

Signature confirms the destruction of product.

Print Name:	
Telephone Number:	
Facsimile Number:	

Please Fax all documents at +370 5 2602142 or email a copy to info.baltics@thermofisher.com.

For any questions or comments please contact Technical Support at +1 (818) 702-0042.

ADDENDUM

With reference to the latest information from HSA on the circulation of FSN, please be informed that the Chairman Medical Board and relevant Head of Departments of the facilities need to be aware of the issues pertaining the medical device used in the facility. Kindly circulate the email to the mentioned parties.

From	:	HSA_MD_Info@hsa.gov.sg
To	:	<Undisclosed recipients:;>
Reply to	:	"HSA MD Info (HSA)" <HSA_MD_Info@hsa.gov.sg>
Subject	:	Field Safety Notices
Date	:	Mon, 27 Feb 2017 16:19:06 +0800

Dear Industry Stakeholders,

With effect from **8 March 2017**, all Field Safety Notices (FSNs) are required to be copied (i.e. include in cc) to the Chairman Medical Board and relevant Head of Departments of the affected local hospitals. This is to ensure that all relevant personnel involved in the management of the hospitals are aware of the issues pertaining to the medical devices used in their facility. This is also to facilitate timely implementation of any recommended follow-up measures and corrective actions by the end-users in the healthcare facilities (e.g. revised instructions for use, updated maintenance requirements etc.).

FSN is a communication sent out by a product owner or its representative to the device users in relation to a Field Safety Corrective Action (FSCA). It is disseminated when the FSCA is initiated for any medical device that has been supplied locally. Currently the FSNs are disseminated by local companies to the appropriate end-users of their medical device. The dissemination of FSN may proceed at the earliest to the users once the FSCA has been reported to HSA.

For more information on FSCA, click here to download the guidance.

Thank you.

Yours Sincerely

MEDICAL DEVICES BRANCH

HEALTH PRODUCTS REGULATION GROUP

HEALTH SCIENCES AUTHORITY